CLAIMS:

1. A gastrointestinal lead adapted to be implanted within the body at a site of the GI tract to conduct electrical stimulation from an implantable or external gastrointestinal stimulator to the site and to conduct electrical signals of the GI tract from the site to the implantable or external gastrointestinal stimulator comprising:

an elongated lead body extending from a lead body proximal end to a lead body distal end;

an electrode head formed at the lead body distal end having a plate adapted to bear against the serosa, the electrode head supporting a first stimulation/sense electrode;

a first lead connector element at the lead body proximal end;

a first lead conductor enclosed within the lead body and electrically coupled to the first stimulation/sense electrode and the first lead connector element; and

an active fixation mechanism extending away from the plate of the electrode head shaped to penetrate through the serosa and into the muscularis externa upon application of force to the electrode head to draw the plate against the serosa and operatively contact the first stimulation/sense electrode with the GI tract wall, whereupon the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall and the active fixation mechanism inhibits dislodgement of the first stimulation/sense electrode from operative contact with the GI tract wall.

2. The gastrointestinal lead of Claim 1, wherein the active fixation mechanism comprises a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix axis, the helix fixed end supported at the plate to extend the helix axis orthogonally to the plate, the helix free end adapted to penetrate through the serosa and the helix adapted to advance into the muscularis externa upon rotation of the helix until the plate is drawn against the serosa.

3. The gastrointestinal lead of Claim 2, wherein the helix has an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

4. The gastrointestinal lead of Claim 2, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

5. The gastrointestinal lead of Claim 2, wherein:

the helix is formed of a conductive electrode material; and

the helix fixed end is electrically coupled to a distal end of the first lead conductor,

whereby the first stimulation/sense electrode comprises at least a portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

6. The gastrointestinal lead of Claim 2, wherein:

the helix is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the helix;

the helix fixed end is electrically coupled to a distal end of the lead conductor,

whereby the first stimulation/sense electrode comprises at least an uninsulated second portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

7. The gastrointestinal lead of Claim 2, wherein the helix fixed end is fixedly attached to the plate, and the electrode head is shaped to be engaged by a fixation tool that is manipulated to rotate the electrode head and helix.

8. The gastrointestinal lead of Claim 2, wherein:

the elongated lead body encloses a stylet lumen extending into the electrode head; and

the electrode head comprises a rotatable mechanism fitted into the electrode head and attached to the helix fixed end to extend the helix axis orthogonally to the plate, the rotatable mechanism adapted to be engaged by a stylet advanced through the stylet lumen, whereby the rotatable mechanism is rotated by the stylet to rotate the helix and advance the helix free end through the serosa and into the muscularis externa until the plate is drawn against the serosa.

9. The gastrointestinal lead of Claim 2, wherein:

the first lead conductor extends from the first lead connector element through a lead conductor lumen and is affixed to the helix fixed end; and

the first lead connector element is rotatable with respect to the lead body to rotate the first lead conductor and the fixation helix, whereby the rotatable lead connector element is rotatable to rotate the helix and advance the helix free end through the serosa and into the muscularis externa until the plate is drawn against the serosa.

10. The gastrointestinal lead of Claim 2, further comprising:

a second lead connector element at the lead body proximal end;

a second stimulation/sense electrode supported by the electrode head spaced from the helix; and

a second lead conductor enclosed within the lead body and electrically coupled to the second stimulation/sense electrode.

11. The gastrointestinal lead of Claim 2, further comprising:

the helix is formed of a conductive electrode material;

the helix fixed end is electrically coupled to a distal end of the first lead conductor, whereby the stimulation/sense electrode comprises at least a portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa;

a second stimulation/sense electrode supported by the electrode head spaced from the helix; and

a second lead conductor enclosed within the lead body and electrically coupled to the second stimulation/sense electrode.

12. The gastrointestinal lead of Claim 1, wherein the first active fixation mechanism comprises a hook comprising a hook shaft extending from a hook fixed end attached to an electrode head to a hook free end spaced from the plate, a sharpened tip formed at the hook free adapted to penetrate through the serosa and to advance into the muscularis externa when insertion force is applied to the electrode head until the plate is drawn against the serosa, whereupon advancement of the hook free end is halted.

13. The gastrointestinal lead of Claim 12, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

14. The gastrointestinal lead of Claim 12, wherein:

the hook is formed of a conductive electrode material; and

the hook fixed end is attached to a distal end of the first lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

15. The gastrointestinal lead of Claim 12, wherein:

the hook is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the hook;

the hook fixed end is attached to a distal end of the first lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

16. The gastrointestinal lead of Claim 12, wherein the plate is substantially planar and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

17. The gastrointestinal lead of Claim 12, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end further away from the plate than the bend.

18. The gastrointestinal lead of Claim 12, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end closer to the plate than the bend.

20. The gastrointestinal lead of Claim 11, wherein the electrode head is shaped to be engaged by a fixation tool that is manipulated to apply the insertion

force to advance the hook free end through the serosa and into the muscularis externa.

21. The gastrointestinal lead of Claim 11, wherein the hook free end is distanced from the plate enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

22. The gastrointestinal lead of Claim 1, wherein the first active fixation mechanism comprises a hook comprising a hook shaft extending from a hook fixed end attached to an electrode head to a hook free end spaced from the plate, a sharpened tip and barb formed at the hook free adapted to penetrate through the serosa and to advance into the muscularis externa when insertion force is applied to the electrode head until the plate is drawn against the serosa, whereupon advancement of the hook free end is halted and the barb engages the muscularis externa to inhibit retraction of the hook.

23. The gastrointestinal lead of Claim 1, wherein:

the active fixation mechanism is formed of a conductive electrode material; and

the active fixation mechanism is electrically coupled to a distal end of the first lead conductor,

whereby the first stimulation/sense electrode comprises at least a portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

24. The gastrointestinal lead of Claim 1, wherein:

the active fixation mechanism is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the active fixation mechanism;

the active fixation mechanism is electrically coupled to a distal end of the first lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

25. The gastrointestinal lead of Claim 1, wherein an anti-inflammatory material selected from the group consisting of steroids, anti-bacterial agents, baclofen, dexamethasone sodium phosphate or beclomethasone phosphate is incorporated into the electrode head or fixation mechanism.

26. The gastrointestinal lead of Claim 1, wherein:

the active fixation mechanism comprises an inner helix and an outer helix, the inner helix comprising one or more coil turn extending from an inner helix fixed end and an inner helix free end adapted to penetrate through the serosa, and the outer helix comprising one or more coil turn extending from an outer helix fixed end and an outer helix free end adapted to penetrate through the serosa; and further comprising:

means for supporting the inner and outer helixes in co-axial relation extending away from the electrode plate

means for rotating the inner and outer helixes to advance the inner and outer helixes into the muscularis externa until the plate is drawn against the serosa.

27. The gastrointestinal lead of Claim 26, wherein the inner and outer helixes have an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the

stomach wall to ensure that the inner and outer helix free ends do not extend substantially through the stomach wall.

28. The gastrointestinal lead of Claim 26, wherein:

the inner helix free end is electrically connected with the first lead conductor to function as the first stimulation/sense electrode; and further comprising:

a second lead connector element at the lead body proximal end; and

a second lead conductor enclosed within the lead body and electrically coupled to the outer helix free end to function as a second stimulation/sense electrode.

29. The gastrointestinal lead of Claim 26, wherein:

the elongated lead body encloses a stylet lumen extending into the electrode head; and

the rotating means comprises a rotatable mechanism fitted into the electrode head and attached to the inner and outer helix fixed ends to extend the inner and outer helixes orthogonally to the plate, the rotatable mechanism adapted to be engaged by a stylet advanced through the stylet lumen, whereby the rotatable mechanism is rotated by the stylet to rotate the inner and outer helixes and advance the inner and outer helix free ends through the serosa and into the muscularis externa until the plate is drawn against the serosa.

30. A gastrointestinal lead adapted to be implanted within the body at a site of the GI tract to conduct electrical stimulation from an implantable or external gastrointestinal stimulator to the site and to conduct electrical signals of the GI tract from the site to the implantable or external gastrointestinal stimulator comprising:

elongated lead body means extending from a lead body proximal end to a lead body distal end;

electrode head means formed at the lead body distal end having stop means adapted to bear against the serosa, the electrode head means supporting a first stimulation/sense electrode;

active fixation means extending away from the electrode head means shaped to penetrate through the serosa and into the muscularis externa upon application of force to the electrode head means to draw the stop means into engagement with the serosa, operatively contact the first stimulation/sense electrode with the GI tract wall, and inhibit dislodgement of the first stimulation/sense electrode from operative contact with the GI tract wall, the stop means inhibiting further advancement of the active fixation means and perforation of the GI tract wall;

connector means at the lead body proximal end adapted to be coupled with an implantable or external stimulator; and

conductor means extending through the lead body for electrically coupling the first stimulation/sense electrode with the connector means.

31. A method of stimulating a site of the GI tract with electrical stimulation from an implantable or external gastrointestinal stimulator and of conducting electrical signals of the GI tract from the site to the implantable or external gastrointestinal stimulator comprising:

surgically accessing the serosa of the GI tract at the site to locate an electrode head of a medical electrical lead oriented to the serosa, the medical electrical lead extending between a connector at a lead body proximal end to an electrode head at a lead body distal end, the electrode head supporting a first electrode and an active fixation mechanism extending from a plate;

perforating the serosa with the active fixation mechanism of the electrode head;

advancing the active fixation mechanism into the muscularis externa to apply the first electrode into operative relation with the GI tract wall and until the

plate bears against the serosa to inhibit further advancement of the active fixation means and perforation of the GI tract wall; and

connecting the connector at the lead body proximal end with an implantable or external stimulator to enable conduction of electrical signals through a lead conductor enclosed within the lead body and electrically coupled to the first stimulation/sense electrode and the connector, whereby the active fixation mechanism inhibits dislodgement of the first stimulation/sense electrode from operative relation with the GI tract wall.

32. The method of Claim 31, wherein the active fixation mechanism comprises a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix axis, the helix fixed end supported at the plate to extend the helix axis orthogonally to the plate, and wherein:

the perforating step comprises penetrating the serosa with the helix free end; and

the advancing step comprises rotating the helix to advance each coil turn into the muscularis externa until the plate is drawn against the serosa.

33. The method of Claim 32, wherein the helix has an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

34. The method of Claim 32, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

35. The method of Claim 32, wherein:

the helix is formed of a conductive electrode material; and

the helix fixed end is electrically coupled to a distal end of the first lead conductor,

whereby the first stimulation/sense electrode comprises at least a portion of the helix that is embedded within the muscularis externa when the plate is drawn against the serosa.

36. The method of Claim 32, wherein:

the helix is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the helix;

the helix fixed end is electrically coupled to a distal end of the first lead conductor,

whereby the first stimulation/sense electrode comprises at least an uninsulated second portion of the helix that is embedded within the muscularis externa when the plate is drawn against the serosa.

37. The method of Claim 32, wherein the helix fixed end is fixedly attached to the plate, and the advancing step comprises engaging the electrode head with a fixation tool and rotating both the electrode head and helix.

38. The method of Claim 31, wherein:

the elongated lead body encloses a stylet lumen;

the electrode head comprises:

a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix axis; and

a rotatable mechanism fitted into the electrode head and attached to the helix fixed end to extend the helix axis orthogonally to the plate;

the perforating step comprises penetrating the serosa with the helix free end; and

the advancing step comprises inserting a stylet into the stylet lumen to engage the rotatable mechanism and rotating the stylet to rotate the helix to

advance each coil turn into the muscularis externa until the plate is drawn against the serosa.

39. The method of Claim 31, wherein:

the electrode head comprises a helix comprising one or more coil turn extending from a helix fixed end fixed to the and a helix free end and having a helix axis;

the elongated lead body encloses a lead conductor lumen enclosing a lead conductor extending from a lead conductor proximal end coupled with the connector and a lead conductor distal end coupled with the helix fixed end;

the perforating step comprises penetrating the serosa with the helix free end; and

the advancing step comprises rotating the lead conductor within the lead conductor lumen to engage the rotatable mechanism to rotate the helix to advance each coil turn into the muscularis externa until the plate is drawn against the serosa.

40. The method of Claim 31, wherein:

the elongated lead body encloses a stylet lumen;

the electrode head comprises:

a first helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a first helix axis;

a second helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a second helix axis co-axially aligned with the first helix axis;

a rotatable mechanism fitted into the electrode head and attached to the first and second helix fixed ends to extend the helix axes orthogonally to the plate;

the perforating step comprises penetrating the serosa with the first and second helix free ends; and

the advancing step comprises inserting a stylet into the stylet lumen to engage the rotatable mechanism and rotating the stylet to rotate the first and second helixes to advance each coil turn into the muscularis externa until the plate is drawn against the serosa.

41. The method of Claim 31, wherein the active fixation mechanism comprises a hook comprising a hook shaft extending from a hook fixed end attached to the electrode head to a hook free end spaced from the plate, a sharpened tip formed at the hook free end, and wherein:

the perforating step comprises penetrating the serosa with the hook free end; and

the advancing step comprises applying force to the electrode head to advance the hook into the muscularis externa until the plate is drawn against the serosa and the barb engages the muscularis externa to inhibit retraction of the hook.

42. The method of Claim 41, wherein the first stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

43. The method of Claim 41, wherein:

the hook is formed of a conductive electrode material; and

the hook fixed end is attached to a distal end of the first lead conductor,

whereby the first stimulation/sense electrode comprises at least a portion of the hook that is embedded within the muscularis externa when the plate is drawn against the serosa.

44. The method of Claim 41, wherein:

the hook is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the hook; and

the hook fixed end is attached to a distal end of the first lead conductor,

whereby the first stimulation/sense electrode comprises at least an uninsulated second portion of the hook that is embedded within the muscularis externa when the plate is drawn against the serosa.

45. The method of Claim 41, wherein the plate is a substantially planar plate and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

46. The method of Claim 41, wherein the plate is a substantially planar plate and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end further away from the plate than the bend.

47. The method of Claim 41, wherein the plate is a substantially planar plate and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end closer to the plate than the bend.

48. The method of Claim 41, wherein the plate is a substantially planar plate and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

49. The method of Claim 41, wherein the electrode head is shaped to be engaged by a fixation tool, and the advancing step comprises applying the

insertion force to advance the hook free end through the serosa and into the muscularis externa through the fixation tool.

50. The method of Claim 41, wherein the hook free end is distanced from the plate enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

51. The method of Claim 31, wherein the active fixation mechanism comprises a hook comprising a hook shaft extending from a hook fixed end attached to the electrode head to a hook free end spaced from the plate, a sharpened tip formed at the hook free end, and wherein:

the perforating step comprises penetrating the serosa with the hook free end; and

the advancing step comprises applying force to the electrode head to advance the hook into the muscularis externa until the plate is drawn against the serosa and the barb engages the muscularis externa to inhibit retraction of the hook.

52. The method of Claim 31, wherein the first stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

53. The method of Claim 31, wherein:

the active fixation mechanism is formed of a conductive electrode material; and

the active fixation mechanism is electrically coupled to a distal end of the first lead conductor,

whereby the first stimulation/sense electrode comprises at least a portion of the active fixation mechanism that is embedded within the muscularis externa when the plate is drawn against the serosa.

54. The method of Claim 31, wherein:

the active fixation mechanism is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the active fixation mechanism; and

the active fixation mechanism is electrically coupled to a distal end of the first lead conductor,

whereby the first stimulation/sense electrode comprises at least an uninsulated second portion of the active fixation mechanism that is embedded within the muscularis externa when the plate is drawn against the serosa.

55. The method of Claim 31, wherein an anti-inflammatory material selected from the group consisting of steroids, anti-bacterial agents, baclofen, dexamethasone sodium phosphate or beclomethasone phosphate is incorporated into the electrode head or fixation mechanism.

56. A system providing gastrointestinal sensing and/or stimulation comprising:

a gastrointestinal lead comprising an elongated gastrointestinal lead body comprising:

an elongated lead body extending from a lead body proximal end to a lead body distal end;

an electrode head formed at the lead body distal end having a plate adapted to bear against the serosa, the electrode head supporting a first stimulation/sense electrode;

a first lead connector element at the lead body proximal end;

a first lead conductor enclosed within the lead body and electrically coupled to the first stimulation/sense electrode and the first lead connector element; and

an active fixation mechanism extending away from the plate of the electrode head shaped to penetrate through the serosa and into the muscularis externa upon application of force to the electrode head to draw the plate against the serosa and operatively contact the first stimulation/sense electrode with the GI tract wall, whereupon the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall and the active fixation mechanism inhibits dislodgement of the first stimulation/sense electrode from operative contact with the GI tract wall;

deploying means for deploying the active fixation mechanism extending away from the plate of the electrode head and penetrating through the serosa and into the muscularis externa to draw the plate against the serosa and operatively contact the stimulation/sense electrode with the GI tract wall, whereby the plate inhibits further advancement of the active fixation mechanism and perforation of the GI tract wall, and the active fixation mechanism inhibits dislodgement of the stimulation/sense electrode from operative contact with the GI tract wall; and

an implantable or external gastrointestinal stimulator having a gastrointestinal stimulator connector coupled with the lead connector assembly to conduct electrical stimulation from the implantable or external gastrointestinal stimulator between the first and second sites of the GI tract and to conduct electrical signals of the GI tract from the first and second sites to the implantable or external gastrointestinal stimulator.

57. The system of Claim 56, wherein;

the active fixation mechanism comprises a helix comprising one or more coil turn extending from a helix fixed end and a helix free end and having a helix axis, the helix fixed end supported at the plate to extend the helix axis orthogonally to the plate; and

the deploying means comprises:

means for pressing the helix free end through the serosa: and

means for rotating the helix to advance the helix into the muscularis externa until the plate is drawn against the serosa.

58. The system of Claim 57, wherein the helix has an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

59. The system of Claim 57, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

60. The system of Claim 57, wherein:

the helix is formed of a conductive electrode material; and

the helix fixed end is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

61. The system of Claim 57, wherein:

the helix is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the helix;

the helix fixed end is electrically coupled to a distal end of the lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

62. The system of Claim 57, wherein the helix fixed end is fixedly attached to the plate, and the electrode head is shaped to be engaged by a fixation tool that is manipulated to rotate the electrode head and helix.

63. The system of Claim 57, wherein:

the elongated lead body encloses a stylet lumen extending into the electrode head; and

the electrode head comprises a rotatable mechanism fitted into the electrode head and attached to the helix fixed end to extend the helix axis orthogonally to the plate, the rotatable mechanism adapted to be engaged by a stylet advanced through the stylet lumen, whereby the rotatable mechanism is rotated by the stylet to rotate the helix and advance the helix free end through the serosa and into the muscularis externa until the plate is drawn against the serosa.

64. The system of Claim 57, wherein:

the first lead conductor extends from the first lead connector element through a lead conductor lumen and is affixed to the helix fixed end; and

the first lead connector element is rotatable with respect to the lead body to rotate the first lead conductor and the fixation helix, whereby the rotatable lead connector element is rotatable to rotate the helix and advance the helix free end through the serosa and into the muscularis externa until the plate is drawn against the serosa.

65. The system of Claim 57, further comprising:

a second lead connector element at the lead body proximal end;

a second stimulation/sense electrode supported by the electrode head spaced from the helix; and

a second lead conductor enclosed within the lead body and electrically coupled to the second stimulation/sense electrode.

66. The system of Claim 57, further comprising:

the helix is formed of a conductive electrode material;

the helix fixed end is electrically coupled to a distal end of the first lead conductor, whereby the stimulation/sense electrode comprises at least a portion of the helix that is embedded substantially within the muscularis externa when the plate is drawn against the serosa;

a second stimulation/sense electrode supported by the electrode head spaced from the helix; and

a second lead conductor enclosed within the lead body and electrically coupled to the second stimulation/sense electrode.

67. The gastrointestinal lead of Claim 57, wherein the first active fixation mechanism comprises a hook comprising a hook shaft extending from a hook fixed end attached to an electrode head to a hook free end spaced from the plate, a sharpened tip formed at the hook free adapted to penetrate through the serosa and to advance into the muscularis externa when insertion force is applied to the electrode head until the plate is drawn against the serosa, whereupon advancement of the hook free end is halted.

68. The gastrointestinal lead of Claim 67, wherein the stimulation/sense electrode is supported on the plate of the electrode head to bear against the serosa when the plate is drawn against the serosa.

69. The gastrointestinal lead of Claim 67, wherein:

the hook is formed of a conductive electrode material; and

the hook fixed end is attached to a distal end of the first lead conductor,

whereby the stimulation/sense electrode comprises at least a portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

70. The gastrointestinal lead of Claim 67, wherein:

the hook is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the hook;

the hook fixed end is attached to a distal end of the first lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the hook that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

71. The gastrointestinal lead of Claim 67, wherein the plate is substantially planar and the hook shaft comprises a first portion extending from the hook fixed end at a first predetermined angle away from the plate and a second portion extending to the hook free end at a second predetermined angle.

72. The gastrointestinal lead of Claim 67, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end further away from the plate than the bend.

73. The gastrointestinal lead of Claim 67, wherein the plate is substantially planar and the hook shaft comprises a first portion and a second portion joined at a bend, the first portion extending from the hook fixed end to the bend at a first predetermined angle away from the plate and a second portion

extending from the bend to the hook free end at a second predetermined angle selected to locate the hook free end closer to the plate than the bend.

74. The gastrointestinal lead of Claim 67, wherein the electrode head is shaped to be engaged by a fixation tool that is manipulated to apply the insertion force to advance the hook free end through the serosa and into the muscularis externa.

75. The gastrointestinal lead of Claim 67, wherein the hook free end is distanced from the plate enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the helix free end does not extend substantially through the stomach wall.

76. The gastrointestinal lead of Claim 56, wherein the first active fixation mechanism comprises a hook comprising a hook shaft extending from a hook fixed end attached to an electrode head to a hook free end spaced from the plate, a sharpened tip and barb formed at the hook free adapted to penetrate through the serosa and to advance into the muscularis externa when insertion force is applied to the electrode head until the plate is drawn against the serosa, whereupon advancement of the hook free end is halted and the barb engages the muscularis externa to inhibit retraction of the hook.

77. The gastrointestinal lead of Claim 56, wherein:

the active fixation mechanism is formed of a conductive electrode material; and

the active fixation mechanism is electrically coupled to a distal end of the first lead conductor,

whereby the first stimulation/sense electrode comprises at least a portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

78. The gastrointestinal lead of Claim 56, wherein:

the active fixation mechanism is formed of a conductive electrode material;

a layer of insulation is formed over a first portion of the active fixation mechanism;

the active fixation mechanism is electrically coupled to a distal end of the first lead conductor,

whereby the stimulation/sense electrode comprises at least an uninsulated second portion of the active fixation mechanism that is embedded substantially within the muscularis externa when the plate is drawn against the serosa.

79. The gastrointestinal lead of Claim 56, wherein an anti-inflammatory material selected from the group consisting of steroids, anti-bacterial agents, baclofen, dexamethasone sodium phosphate or beclomethasone phosphate is incorporated into the electrode head or fixation mechanism.

80. The gastrointestinal lead of Claim 56, wherein:

the active fixation mechanism comprises an inner helix and an outer helix, the inner helix comprising one or more coil turn extending from an inner helix fixed end and an inner helix free end adapted to penetrate through the serosa, and the outer helix comprising one or more coil turn extending from an outer helix fixed end and an outer helix free end adapted to penetrate through the serosa; and further comprising:

means for supporting the inner and outer helixes in co-axial relation extending away from the electrode plate

means for rotating the inner and outer helixes to advance the inner and outer helixes into the muscularis externa until the plate is drawn against the serosa.

81. The system of Claim 80, wherein the inner and outer helixes have an axial length enabling a depth of penetration from the plate in the range of 1 mm to 15 mm when the site comprises the antrum of the stomach wall or in the range of 1 mm to 10 mm when the site comprises corpus or fundus of the stomach wall to ensure that the inner and outer helix free ends do not extend substantially through the stomach wall.

82. The system of Claim 80, wherein:

the inner helix free end is electrically connected with the first lead conductor to function as the first stimulation/sense electrode; and further comprising:

a second lead connector element at the lead body proximal end; and

a second lead conductor enclosed within the lead body and electrically coupled to the outer helix free end to function as a second stimulation/sense electrode.

83. The system of Claim 80, wherein:

the elongated lead body encloses a stylet lumen extending into the electrode head; and

the rotating means comprises a rotatable mechanism fitted into the electrode head and attached to the inner and outer helix fixed ends to extend the inner and outer helixes orthogonally to the plate, the rotatable mechanism adapted to be engaged by a stylet advanced through the stylet lumen, whereby the rotatable mechanism is rotated by the stylet to rotate the inner and outer helixes and advance the inner and outer helix free ends through the serosa and into the muscularis externa until the plate is drawn against the serosa.